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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,277	02/02/2005	Igor Shvets	1817-0150PUS1	9349
2292 7590 06/13/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	
			NOTIFICATION DATE	DELIVERY MODE
			06/13/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/500,277	Applicant(s) SHVETS ET AL.	
	Examiner ANN Y. LAM	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-89 is/are pending in the application.
- 4a) Of the above claim(s) 56-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2/05, 6/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 54 is objected to because of the following informalities: in line 3, --at— should be inserted after “connected”; and in line 4, --respectively—should be inserted before the period. Appropriate correction is required.

Election/Restrictions

Applicant's election with traverse of the restriction requirement in the reply filed on March 24, 2008 is acknowledged. The traversal is on the ground(s) that there would be no burden on Examiner if all the claims were examined in a single application. This is not found persuasive because the groups require search and consideration for limitations that vary in the different groups, and it is noted that there are 89 claims pending in the present application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 56-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47-51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard, 5,580,523, in view of Dovichi et al., 5,567,294.

Bard discloses an integrated chemical synthesizer system that is modular in design, and allows for the use of one or more of the same type of reactor, or a variety of different types of reactors, each having microliter capacity. The reactors can be used individually, together, and interchangeably with one another can be thermal, electrochemical, catalytic, enzymatic, photochemical or hollow chamber type. The modular nature of the system, component parts, e.g., the reactors, flow channels, sensors, detectors, allows easy replacement and/or interchangeability of the component parts and provides for versatility. See column 2, lines 33-47, and column 4, lines 53-64. For example, it should be easier to scale-up reactions because one would simply add additional modules of exactly the same type to increase output. See column 2, lines 61-67.

Bard further discloses that the reactor design is developed to form a reactor chamber having an ID [which appears to refer to a dimension] less than 100 μm . The chamber is covered and the unit mounted on an assembly board containing fluid conveying channels, with fastening means, to provide for flow to and from the reactor

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chamber. See column 3, lines 39-44. The plurality of interchangeable reaction vessels are capable of handling reaction volumes from about 1 nL up to about 10 uL. Column 3, lines 45-50.

There can be included flow control components such as pumps, flow channels, manifolds, flow restrictors, valves, etc., with necessary fittings that allow them to be sealed with the pre-arranged or selectively located flow channels or connectors. The reaction units, can be chip like. See column 4, lines 35-46, and column 6, line 67. An exemplary embodiment includes an assembly of different chips (60, 70, 100, see fig. 3) on a single assembly board 80), wherein the chips are respectively a reactor, a separator and an analyzer, and each include the requisite structures and components to perform the designated process, e.g., separation and analysis. See column 6, lines 34-40. The assembly board also has channels (81-84 which communicate with the channels of the chips. Capillary tubings for reactors, detectors, etc., may be assembled on a support board. See column 6, lines 41-52.

With respect to claims 47-49, the Bard reactors/chips are equivalent to Applicant's biochips (60, 70, 100), each with at least one microchannel (see chips in fig. 3; see also column 3, lines 45-50, describing the nanoliter and microliter reaction volumes), the microchannel having an inlet port at one end and outlet port at the other end. The assembly board with the channels/capillaries (e.g., 81-84) are equivalent to Applicant's liquid delivery unit having a plurality of liquid delivery ports, one for connection to each biochip. The "necessary fittings" to allow a seal between the respective channels in the chips and assembly board (col. 4, lines 39-41) are equivalent

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to a connection means, and the fittings are releasable since it is disclosed that the chips/reactors can be used interchangeably with one another (col. 2, lines 39-41.) The channels/capillaries in the assembly board are equivalent to separate enclosed transfer conduits. Bard disclose that the transfer conduits transfer fluids from chip to chip (see figure 3.)

However, Bard does not disclose well(s) in which a releasable connection means provide for transfer of fluid between the well and a chip. Bard does not appear to disclose how fluids/reagents/samples are introduced into the chips in the first place, that is, other than through transfer from chip to chip. However, Dovichi et al. teach one method of doing so.

Dovichi et al. teach using capillary tubes (26) to transfer fluids from wells (30) to an analyzer (20). See column 3, lines 33-37 and column 5, lines 17-20. Conductive elements and an electric field may be used to move molecules (col. 5, lines 17-20) or other means such as mumps can be used (col. 7, lines 1-4.) The number of capillary tubes can vary, for example 96 capillaries in a 12 by 8 array may be used to interface with a 96 well microtiter plate, or other arrays can be designed as needed. See col. 7, lines 5-10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide capillary tubes to transfer fluids from microtiter plate wells to the multiple chips in the Bard assembly, in order to provide the fluid reagents to the chips as necessary for a particular analysis, as taught by Dovichi et al. While Dovichi et al. do not disclose multiple chips, the skilled artisan would recognize that in

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modifying the Bard assembly to include capillaries to introduce reagents from microtitre plate wells, the capillaries, connected at one end to the wells of the microtiter plate, can be connected at the other end to more than just one chip in order to attain the same purpose of introducing reagents into the chips for performing an analysis. While Bard does disclose providing a cover (12) to close the upper surface of the reactor to produce the finished chip (col. 5, lines 37-39), the skilled artisan would recognize that providing capillaries for introducing fluid reagents from microtiter wells as taught by Dovichi et al. would not depart from the basic concept of the Bard invention, i.e., to produce a modular system with components, e.g., reactors, separation chambers, analyzers, etc., that are easily assembled (col. 5, lines 1-4.) And the skilled artisan would have reasonable expectation of success since it is within the skills of the ordinary artisan to utilize connections and valves, such as those discussed by Bard (col. 4, lines 35-46) as well as Dovichi et al. (col. 7, lines 1-4), to interconnect the modified assembly such that fluids can be transferred from one place to another, and channels can be closed, etc.

As to claim 49, the top of each well is equivalent to a port.

As to claims 50 and 51, Bard teaches that the biochips can include flow channels, manifolds, valves, etc., as necessary for a particular purpose (col. 4, lines 35-46), that can be sealed with other flow channels or connectors. The skilled artisan would have recognized that each chip can be formed such that they have more than one inlet port and more than one outlet port, each capable of being connected to a different liquid delivery unit, as necessary for transferring the requisite reagents to carry out a particular analysis. Such modifications are within the skills of the ordinary artisan as they are

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based on the same principles as taught by the references, i.e., transferring fluid from a microtiter well to a chip (as taught by Bard), in addition to capillaries that transfer fluid from one chip to another (as taught by Dovichi et al.) The skilled artisan would have reasonable expectation of success since flow control means such as pumps and valves are well known and are also suggested by Bard (col. 4, lines 35-46) as well as Dovichi et al. (col. 7, lines 1-4), and the above modifications involve providing the requisite capillaries and such flow control means.

As to claim 54, the disclosed Bard microchannel can be considered to be formed of two connected microchannels, one microchannel having an inlet (i.e., the opening at its proximal end) and an outlet port (i.e., the opening at its distal end), which is connected to the second microchannel at that microchannels inlet.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bard, 5,580,523, in view of Dovichi et al., 5,567,294, as applied to claim 49 above, and further in view of Yon-Hin et al., 6,440,645.

Bard and Dovichi et al. has been discussed above. However, neither disclose a Y-shaped microchannel.

Yon-Hin et al. disclose a chip having microfluidic channels, including an embodiment with a Y-shaped channel (see figure 4). Providing such channel shape as disclosed by Yon-Hin in the Bard chip is well within the skills of the ordinary artisan for any of various reasons, such as allowing for the introduction of reagents from two

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different inlets. The skilled artisan would have reasonable expectation of success since forming such channels involves the same photolithography and micromachining methods discussed by Bard (see col. 5, lines 44-48) 4. See also discussion of photolithography in column 4, lines 65-66, in the Yon-Hin et al. reference.

Claims 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard, 5,580,523, in view of Dovichi et al., 5,567,294, and further in view of Parce et al., 5,942,443.

Bard in view of Dovichi et al. have been discussed above (see claim 47) which is equally applicable to claims 53 and 55. However, neither Bard nor Dovichi et al. disclose that the microchannel of the chip has at least one intermediate portion of which has a different cross-sectional area to that of the rest of the microchannel (claim 53), or that the transfer conduits have internal cross sectional area substantially greater than that of each microchannel (claim 55.)

Parce et al. teach microfluidic devices and specifically disclose that flow resistance can generally be adjusted by adjusting channel length or width (col. 20, lines 6-7 and 12-14.) As to claim 53, the skilled artisan would have had knowledge regarding basic fluid dynamics as disclosed by Parce et al., and thus it is within the skills of the ordinary artisan to provide microchannels in the chip having an intermediate portion with a width (or cross-sectional area) that is different from the rest of the microchannel as

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may be desired for workable or optimum fluid flow. Likewise, as to claim 55, it is within the skills of the ordinary artisan to provide transfer conduits having internal cross sectional area substantially greater than that of each microchannels as may be desired for workable or optimum fluid flow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ann Y. Lam/
Primary Examiner, Art Unit 1641